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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,247	09/08/2003	John W. Dohner	ARC 2363 N3	4124
27777	7590	08/23/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			HOWARD, SHARON LEE	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/658,247

Applicant(s)

DOHNER ET AL.

Examiner

Sharon L. Howard

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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*The examiner acknowledges receipt of the Preliminary Amendment and the Remarks filed on 9/8/03.*

### **Status of the Claims**

*Claims 1-26 have been cancelled and new claims 27-32 have been added.*

*Claims 27-32 are pending in this application.*

### **Claim Objections**

Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

### **Double Patenting**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 27 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5,662,928. This is a double patenting rejection.

Claim 1 of the U.S. Patent No. '928 which recites a process for the production of a scopolamine free base containing transdermal system substantially free of crystals of scopolamine free base, comprising annealing scopolamine free base containing layers

of said transdermal system at a temperature of at least 67 degrees C for about 5 minutes- about 15 minutes within about 24 hours of casting a scopolamine free base containing formulation onto a web for use in constructing said transdermal system is the same as that of claim 27 of the instant application. Claim 12 of the U.S. Patent No. '928 which recites that annealing takes place for a scopolamine containing contact adhesive layer over a period of about 5-15 minutes is the same invention as claim 27.

Claim 28 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. '928. This is a double patenting rejection. Claim 2 recites that the transdermal system is further packaged and further heat treated at a temperature of at least 67 degrees C to about 90 degrees C for a period of about 12 to about 36 hours which overlaps the range of a period of about 4 hours to about 24 hours.

Claim 29 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. '928. This is a double patenting rejection. Claim 2 recites that the transdermal system is further packaged and further heat treated at a temperature of at least 67 degrees C to about 90 degrees C for a period of about 12 to 36 hours, and 75 degrees C to about 90 degrees C overlaps the range of 67 degrees C to about 90 degrees C. Claim 7 recites annealing takes place at about 67 degrees C to about 90 degrees C which is the same temperature range claimed in claim 29.

Claim 30 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. '928. This is a double patenting rejection. Claim 30 is claiming annealing takes place over a period of about 2-10 minutes which encompasses the range of about 5 minutes – about 15 minutes recited in claim 1.

Claim 31 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 15 of prior U.S. Patent No. '928. This is a double patenting rejection. Claim 15 which recites a drug reservoir layer containing scopolamine free base and a contact adhesive layer containing scopolamine free base are each separately annealed, then contacted and further annealed prior to packaging is the same invention as claim 31.

Claim 32 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 19 of prior U.S. Patent No. '928. This is a double patenting rejection. Claim 19 which recites in a method for manufacturing delivery devices for the transdermal administration of scopolamine which comprises, in combination: a. forming a laminate, at least one lamina of which comprises a dispersion of said scopolamine in a non-aqueous matrix; b. cutting subunits forming said delivery devices from said laminate; c. packaging said delivery devices in sealed containers; d. heating said delivery devices in said containers to a temperature above the melting point of crystalline scopolamine hydrate and maintaining said delivery devices at such temperature for a time sufficient to prevent the formation or eliminate the presence of crystals of scopolamine hydrate for a substantial period of time after cooling of the subunits to ambient temperatures; and e. cooling the delivery devices to ambient temperature; the improvement comprising heating at least each scopolamine containing layer to a temperature exceeding the melting point of scopolamine crystal for a period of time sufficient to melt the crystals which improvement heating step is conducted prior to but within about 24 hours, or during the process, or laminating and/or sealing the scopolamine containing layer is the same as that of claim 32 of the instant application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard  
August 17, 2004

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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